

REMARKS

I. Patentability Arguments

A. The Rejections Under 35 U.S.C. § 102 (b) and (e) Should Be Withdrawn

The Examiner maintained the rejection of claims 26, 41, 42, 44-45 under 35 USC § 102(b) as being anticipated by EP 0569 678 A2 to Eisenbach *et al* (Eisenbach 1), alleging at paragraph 3 on page 2 of the Office Action that,

the term “genomic DNA” as recited in the instantly claimed invention has not been adequately defined in the specification, therefore because the MHC determinants used by Eisenbach *et al.* were derived from the genome of a tumor cell of a mouse, hence “genomic DNA,” one of skill in the art would have anticipated that the limitation of transfecting an antigen presenting cell with a genomic DNA was also encompassed within the scope of the claims, wherein the genomic DNA used Eisenbach *et al.* was the DNA encoding the MHC determinant being transfected into the cell.

Applicant respectfully disagrees with the Examiner that the term “genomic DNA” is not adequately defined in the instant specification which at pages 30 and 31 teaches in detail how the entire genomic DNA is isolated from tumor cells for transfection according to the present invention. The term is also well known to a person skilled in the relevant art and requires no more definition. As to the distinction between genomic DNA and the DNA used by Eisenbach, the Examiner himself has pointed out that the DNA transfected by Eisenbach is “derived” from genomic DNA. The Eisenbach DNA is cloned cDNA, inserted into expression vectors and is not genomic DNA as it is known in the art and as is described in the present specification.

Because Eisenbach 1 does not teach transfecting cells with genomic but rather uses cloned genes, it cannot properly anticipate the present invention, and therefore the rejection should be withdrawn.

The Examiner also maintained the rejection of claims 26, 41, 42, 44-45 under 35 USC § 102(e) as being anticipated by U.S. Patent 5,750,102 to Eisenbach *et al.* (Eisenbach 2) essentially for the same reasons as he provided for Eisenbach 1 reference. As discussed above, the present invention requires transfection of cells with genomic DNA in contrast to Eisenbach 2, who uses cloned DNA, and therefore the reference cannot anticipate the present invention and thus the rejections may properly be withdrawn.

B. The Rejections Under 35 U.S.C. § 112, First Paragraph, Should Be Withdrawn

In paragraph 5 on page 3 of the Office Action, the Examiner, citing several publications, has rejected claims 47-53 under 35 U.S.C. 112, first paragraph, because, according to the Examiner "the specification, while being enabling for a method of treating a tumor, ... does not reasonably provide enablement for a method of preventing the recurrence of a tumor."

Applicant submits that the instant specification fully enables claims 47-53 as demonstrated, for example, in Example 15 at pages 72-74 of the specification.

In that Example, surviving mice who had previously been injected with both breast tumor cells and a breast cancer vaccine prepared according to the methods of the present invention were challenged with a second injection of breast cancer cells. Naïve mice (mice who had not become exposed to either the vaccine or the breast tumor cells) were also injected with breast cancer cells with no vaccine and both groups were monitored for survival. The mean survival time of those mice who were previously vaccinated vaccine, was significantly higher than those mice who had not previously received the vaccine ($P < .02$) suggesting that the previously treated mice had developed at least partial immunity against subsequent tumor challenge.

In view of the foregoing and because the instant specification provides working examples supporting the conclusion that the methods of the instant invention are able to extend the life expectancy of mice upon subsequent challenge with tumor cells, the Applicant submits that the claims are enabled and therefore requests that the rejection of claims 47-53 under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and early notification thereof is requested. If in the interest of expediting prosecution, the Examiner has questions or comments he is invited to telephone the undersigned at the indicated telephone number.

Respectfully submitted,

HOWREY SIMON ARNOLD & WHITE, LLP

By: _____

David W. Clough, Ph.D.
Registration No.: 36,107

Dated: April 26, 2004
321 N. Clark Street, Suite 3400
Chicago, IL 60610
Telephone: (312) 595-1408
Fax: (312) 595-2250